

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kündig et al.
 Appl. No. : 09/380,534
 Filed : September 1, 1999
 For : A METHOD OF INDUCING
 A CTL RESPONSE
 Examiner : Michael Hayes

Group Art Unit: 3763

I hereby certify that this correspondence and all
 marked attachments are being deposited with the
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 Patents, Washington, D.C. 20231, on

February 28, 2002

(Date)

Dale C. Hunt, Reg. No. 41,857

DECLARATION OF DAVID C. DIAMOND
UNDER RULE 132

Assistant Commissioner for Patents
 Washington, D.C. 20231

Dear Sir:

I, David C. Diamond, declare and state:

1. I am a Ph.D. scientist and patent agent employed by the assignee of the above-referenced patent application. I am familiar with the specification, claims, and prosecution history thereof. I hold a Bachelor's degree in biochemistry from Brandeis University. I earned a Ph.D. in molecular biology at SUNY Stony Brook where my dissertation was on the antigenic structure of poliovirus. As a Research Fellow in the Immunology Department of Harvard Medical School I pursued training in cellular immunology at the Dana-Farber Cancer Institute where my work focused on antigen processing as well as the interaction of CD4 with HIV gp120. In my career I have engaged in research in antibody engineering, gene therapy, xenotransplantation and histocompatibility. I am an author of over a dozen peer-reviewed articles, including publications in *Science* and the *Proceedings of the National Academy of Science*, as well as 11 book chapters, several dealing with vaccine design.

2. I have read the Office Action mailed on December 1, 2001, and the cited references. I understand that an interview took place at the U.S.P.T.O. between Dale C. Hunt and the Examiner on January 24, 2002. I understand that, during the interview, the Examiner

raised the issue of possible inherent anticipation of the claims in view of Martins et al. ("Martins") (U.S. Patent No. 4,455,142). For the reasons set forth below, I declare and state that the disclosure of Martins would not inherently result in the induction of a cytolytic T lymphocyte (CTL) response.

3. For a result to be inherent to a method, the result must be necessarily produced, not merely possibly or even probably produced. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) and M.P.E.P. § 2112.

4. The disclosure of Martins would not, as a necessary result, lead to the induction of a CTL response. There are various scenarios in which practice under Martins likely would not result in induction of a CTL response. There are other scenarios in which Martins clearly would not result in induction of a CTL response. Set forth below are two exemplary situations where following the teachings of Martins clearly would not, as a necessary result, lead to the induction of a CTL response.

5. The two scenarios use peptide antigens. Peptide antigens fall within the Martins definition of antigen. Martins includes in its description of antigen "a hydrolyzed or breakdown product prepared by acid digestion, extraction, or enzymatic digestion of the above, or it may be a synthetic product representing part of their structure." Column 4, lines 4-7. Peptides clearly fall within such a definition.

6. **Example 1.**

If the antigen administered according to Martins is a hexamer peptide, it will be long enough to elicit an antibody response, but will be too short to induce any kind of T cell response.

7. **Example 2.**

~~If the antigen administered according to Martins is a nonamer peptide, but the peptide does not bind to any of the class I MHC molecules expressed by the animal to be immunized (that is it lacks the appropriate MHC-binding motifs), no CTL response will be induced.~~


8. It is conventional in the art to conjugate carrier proteins with certain antigens, particularly small antigens, such as those listed in Examples 1 and 2. However, with or without conjugation, neither of the antigens discussed in Examples 1 and 2 could inherently result in induction of a CTL response.

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9. Examples 1 and 2 present two operative scenarios wherein following the practice of Martins clearly would not result in induction of a CTL response. Thus, a CTL response is not an inherent feature of Martins because there are multiple conventional scenarios in which, precisely following the teachings of Martins, one clearly would not be able to obtain a CTL response. It follows that there is no inherent anticipation of the claims under Martins.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity and/or enforceability of the application and/or any patent issuing therefrom.

Dated: 2/28/02

Signed: 
David C. Diamond

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